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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,747

03/22/2005

Robert H Shoemaker

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1785

45115

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06/25/2008

TOWNSEND AND TOWNSEND AND CREW, LLP  
TWO EMBARCADERO CENTER  
8TH FLOOR  
SAN FRANCISCO, CA 94111

EXAMINER

SNYDER, STUART

ART UNIT

PAPER NUMBER

1648

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,747	<b>Applicant(s)</b> SHOEMAKER ET AL.	
	<b>Examiner</b> STUART W. SNYDER	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-16 is/are allowed.
- 6) ☒ Claim(s) 18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/6/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Status of the Claims*

1. Amendment of claims 1 and 18 and cancellation of claim 17 in Applicants' filing of 3/3/2008 is acknowledged; claims 1-16 and 18-19 are pending and examined herein.

### *Claim Rejections - 35 USC § 112*

2. Rejection of claims 1, 2, 7, and 9-16 under 35 USC § 112, first paragraph as lacking enablement is **withdrawn** in view of the amendment to the claim, Dr. Shoemaker's 17 CFR § 1.132 Declaration filed 3/3/2008 and Applicants' arguments; rejection of claim 17 is moot and **withdrawn** in view of cancellation of the claim.
3. Rejection of claim 17 under 35 USC § 112, second paragraph as lacking sufficient antecedent basis and improperly broadening the scope of the claim is moot and **withdrawn** in view of cancellation of the claim.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Rejection of claims 1, 7, 8, 18 and 19 under 35 U.S.C. 102(b) as being anticipated by Wasfi and Johnson is **withdrawn** in view of Applicants' arguments.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Rejection of claims 9 and 15 under 35 U.S.C. 103(a) as being unpatentable over Wasfi and Johnson is **withdrawn** in view of Applicants' arguments; rejection of claim 17 is moot and **withdrawn** in view of cancellation of the claim.
6. Rejection of claims 10-14 under 35 U.S.C. 103(a) as being unpatentable over Wasfi and Johnson in view of Hermans is **withdrawn** in view of Applicants' arguments.
7. Claims 18 and 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Napier, et al. 5. The claims are drawn to a pharmaceutical composition comprising a therapeutically effective unit dose of a compound of Claim 1; claim 19 adds the further limitation that the composition further comprises an excipient.  
  
Napier, et al. teaches such a composition, acetyl-para-aminophenyl-stibiate, in the treatment of Kala-azar and trypanosomiasis:

"In 1916 Caronia treated four cases of kala-azar with an organic compound of antimony, acetyl-para-aminophenyl-stibiate of soda, with apparent cure of three of the cases by intramuscular injections of the drug, and in 1920 Mason-

Bahr reported encouraging results with this preparation in a case of kala-azar and in one of trypanosomiasis." (see page 44).

Thus, Napier, et al. teaches all the limitations of claim 18.

Furthermore, it has become common practice in the pharmaceutical industry to include excipients to pharmaceutical compositions for various reasons: Some excipients, such as buffering agents, increase the stability of the active ingredient(s); some excipients, such as monosaccharides, are added to increase the bulk of powdered therapeutic compositions so that consistent dosing of the active ingredient is more easily achieved, and some excipients are added to make the therapeutics more palatable, such as the flavorings added to nicotine gum. Thus, the invention of claims 18 and 19 are anticipated by Napier, et al. and obvious in view of the routine practice of including excipients to pharmaceutical therapeutics.

#### ***Allowable Subject Matter***

8. Claims 1-16 are allowed.

#### ***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./  
Primary Examiner, Art Unit 1648

Stuart W Snyder  
Examiner  
Art Unit 1648

SWS